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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	C7979U	5826

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EXAMINER	
WELTER, RACHAEL E	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/673,872	WAI-CHIU SO ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8,12-16,19,21,23,24,26,29 and 139-163* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,12-16,19,21,23,24,26,29 and 139-163* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/10 has been entered.

Claim Status

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-163 are pending. Claims 2, 5-7, 9-11, 17-18, 20, 22, 25, 27-28, and 30-138 are cancelled. Claims 162-163 are newly added.

Withdrawn Rejections

The rejection of claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202) is withdrawn in light of applicant's amendments.

The rejection of claims 140, 145, 152, and 161 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of Yu et al (EP0273202)

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as applied to claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, 139, 141-144, 146-151, and 153-160 above and in further view of Uchikawa et al (5,156,836) is withdrawn in light of applicant's amendments.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-163 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendments of independent claims 1 and 21 in the response filed 2/3/10 do not comply with the written description requirement and introduce new matter into the patent application. The claims recite that minoxidil is the sole hair-growing active present in the composition and that the minoxidil or salt thereof is not encapsulated. The reply filed 2/3/10 states that support for this amendment is found throughout the specification and claims as originally filed. Applicant has not pointed out where and/or

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how the originally filed disclosure of the instant application supports the amendments. Applicant should show support in the original disclosure for the new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure.").

Nevertheless, it is noted that there is insufficient support for unencapsulated minoxidil as the sole active. According to MPEP 2173.05 (i), "Any negative limitation or exclusionary proviso must have basis in the original disclosure." Nowhere in the instant specification does applicant explicitly state these limitations. Applicant is reminded that in order to have adequate support for new limitations, applicant must prove that the specification clearly states and/or exemplifies that the inventors considered the limitation to be a part of their invention at the time of filing. Thus, the mere absence of a positive recitation in the instant specification (i.e., unencapsulated minoxidil as the sole active) is not a basis for exclusion in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-4, 8, 12-16, 19, 26, 29, 139, 141, 143-144, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached Herein; Published: 1998) in view of Yu et al (EP0273202).

JP '343 teaches topical preparations wherein monoxidil and dipropylene glycol are blended (claim 1; paragraph 0005). Dipropylene glycol is 5-40 wt.% of the pharmaceutical preparation and other polyhydric alcohols chosen from 1,3-butylene glycol and propylene glycol can be added as well in an amount of 0.1-10 wt.% (claim 7).

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The preparation has a preferred pH of 5-8 (paragraph 0010). Minoxidil is present in the preparation in an amount of 0.1-10 wt.% (claim 2). The preparation also comprises 0.5-30 wt.% water and 50-90 wt.% lower alcohol (ethanol and isopropyl alcohol) (paragraph 0014). The preparation can be used for external preparations, such as cream pharmaceuticals, ointments, aerosols, and lotions (paragraph 0015). Emulsifiers, higher alcohols (2-hexyl-1-decanol and isooctadecanol), perfumes, cooling agents, and color can also be blended into the preparations (paragraph 0013).

JP '343 does not teach the instant acid salt.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Peck and Yu et al and utilize the instant acid. One would be motivated to do so since Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

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Regarding the limitations directed to the amount of minoxidil, JP '343 teaches minoxidil in an amount of 0.1-10%. Thus, it would have been obvious to a skilled artisan at the time the invention was made to manipulate the concentration of minoxidil during routine optimization in order to achieve a concentration of at least 5% and more specifically, 7.5 to 12% by weight. One would have been motivated to do so depending on the dosage strength and the needs of a particular patient population. Drug concentration is a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).*

Regarding the instantly claimed ratio of ethanol to water, JP '343 sets forth a general range of components wherein the alcohol is utilized in an amount of 50-90 wt.% and water from 0.5-30 wt.%. Thus, it is within the skill of an artisan to look at the guidance provided by JP '343 and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

Regarding the limitation, wherein "propylene glycol is present in an amount of less than 5%" and newly added claim 162, "wherein the composition is free of propylene

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glycol," it is noted that JP '343 teaches that 1,3-butylene glycol OR propylene glycol can be added in its preparation in an amount of 0.1-10 wt.%. Therefore, JP '343 suggests the absence of propylene glycol. Additionally, JP '343 suggests that the compound can be present at less than 5% since 0.1-10 wt.% encompasses the instant amount. According to MPEP 2144.05, "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Regarding the limitation, "wherein the pharmaceutical composition upon actuation with a propellant forms a foam or mousse," it is noted that this limitation is intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In this case, since the combined prior art suggest all the components of the instant claims, the prior art structure is capable of performing a form or mousse with the addition of a propellant. If the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).*

Claims 21, 23-24, 146-151, 153-157, 159-160, and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached

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Herein; Published: 1998) in view of Yu et al (EP0273202) and Chow et al (US Patent No. 4,515,810; Published 5/7/1985).

JP '343 teaches topical preparations wherein monoxidil and dipropylene glycol are blended (claim 1; paragraph 0005). Dipropylene glycol is 5-40 wt.% of the pharmaceutical preparation and other polyhydric alcohols chosen from 1,3-butylene glycol and propylene glycol can be added as well in an amount of 0.1-10 wt.% (claim 7). The preparation has a preferred pH of 5-8 (paragraph 0010). Minoxidil is present in the preparation in an amount of 0.1-10 wt.% (claim 2). The preparation also comprises 0.5-30 wt.% water and 50-90 wt.% lower alcohol (ethanol and isopropyl alcohol) (paragraph 0014). The preparation can be used for external preparations, such as cream pharmaceuticals, ointments, aerosols, and lotions (paragraph 0015). Emulsifiers, higher alcohols (2-hexyl-1-decanol and isooctadecanol), perfumes, cooling agents, and color can also be blended into the preparations (paragraph 0013).

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Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Peck and Yu et al and utilize the instant acid. One would be motivated to do so since Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

Additionally, JP '343 does not utilize a propellant to form a foam or mousse. JP '343 only teaches that its external preparations can be used as aerosols.

Chow et al teach quick-breaking foam formulations to deliver topical medicaments (abstract; column 3, lines 65-68--column 4, lines 1-2). Propellants utilized in its formulations include hydrocarbons, such as propane, isobutane or mixtures thereof (column 7, lines 63-64). Chow et al teach that foams have advantages over creams or ointments because they have a neater appearance and are easier to use than other topical preparations (column 5, lines 60-67). According to Chow et al, foams enable the medication to be administered quickly and the proper dose to be effectively controlled via a metered valve (column 5, lines 60—column 6, lines 1-2).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to utilize a propellant within the compositions of JP '343 to form a foam or mousse. One would have been motivated to do so since JP '343 discloses that its compositions can be formulated as aerosols and Chow et al teach that foams have a neater appearance and are easier to use than other topical preparations.

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Therefore, a skilled artisan would have been motivated to formulate the preparation into a foam for the obvious reason of increasing patient compliance.

Regarding the limitations directed to the amount of minoxidil, JP '343 teaches minoxidil in an amount of 0.1-10%. Thus, it would have been obvious to a skilled artisan at the time the invention was made to manipulate the concentration of minoxidil during routine optimization in order to achieve a concentration of at least 5% and more specifically, 7.5 to 12% by weight. One would have been motivated to do so depending on the dosage strength and the needs of a particular patient population. Drug concentration is a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).*

Regarding the instantly claimed ratio of ethanol to water, JP '343 sets forth a general range of components wherein the alcohol is utilized in an amount of 50-90 wt.% and water from 0.5-30 wt.%. Thus, it is within the skill of an artisan to look at the guidance provided by JP '343 and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

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Regarding the limitation, wherein "propylene glycol is present in an amount of less than 5%" and newly added claim 163, "wherein the composition is free of propylene glycol," it is noted that JP '343 teaches that 1,3-butylene glycol OR propylene glycol can be added in its preparation in an amount of 0.1-10 wt.%. Therefore, JP '343 suggests the absence of propylene glycol. Additionally, JP '343 suggests that the compound can be present at less than 5% since 0.1-10 wt.% encompasses the instant amount. According to MPEP 2144.05, "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Claims 152 and 161 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached Herein; Published: 1998) in view of Yu et al (EP0273202) and Chow et al (US Patent No. 4,515,810; Published 5/7/1985) as applied to claims 21, 23-24, 146-151, 153-157, 159-160, and 163 above and in further view of Uchikawa et al (5,156,836).

Claims 140 and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached Herein; Published: 1998) in view of Yu et al (EP0273202) as applied to claims 1, 3-4, 8, 12-16, 19, 26, 29, 139, 141, 143-144, and 162 above and in further view of Uchikawa et al (5,156,836).

The teachings of JP '343, Yu et al, and/or Chow et al have been set forth above.

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JP '343, Yu et al, and/or Chow et al not teach the elected glycerol co-solvent or utilize an antioxidant.

Uchikawa teaches a hair revitalizing composition that may comprise minoxidil. Uckikawa teaches conventional excipients used to formulate hair-revitalizing compositions include polyhydric alcohols such as glycerine and propylene glycol, antioxidants, etc. see column 4, lines 5-30.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the exemplified propylene glycol with the instantly claimed glycerol and arrive at the instant invention. One would have been motivated to do so since Uchikawa teaches both propylene glycol and glycerol are polyhydric alcohols conventionally used in the art. Therefore, a skilled artisan would have expected similar results absent unexpected results by using any conventional polyhydric alcohol known in the art in the composition. Further, it would have been obvious for a skilled artisan to further utilize a conventional excipient such as an antioxidant as taught by Uchikawa in the composition of JP '343. One would have been motivated to do so in order to prevent oxidation and degradation.

Claim 158 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached Herein; Published: 1998) in view of Yu et al (EP0273202) and Chow et al (US Patent No. 4,515,810; Published 5/7/1985) as applied

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to claims 21, 23-24, 146-151, 153-157, 159-160, and 163 above and in further view of Peck et al (WO 88/01863).

Claim 142 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-265343 (Machine Translation Attached Herein; Published: 1998) in view of Yu et al (EP0273202) as applied to claims 1, 3-4, 8, 12-16, 19, 26, 29, 139, 141, 143-144, and 162 above and in further view of Peck et al (WO 88/01863).

The teachings of JP '343, Yu et al, and/or Chow et al have been set forth above.

JP '343, Yu et al, and/or Chow et al not utilize Polysorbate 60.

Peck teaches a quick breaking foam to treat baldness comprising 1-5% minoxidil and various surfactants including Tween 80 (polysorbate) and Span 60 to improve the stability of the composition (pg. 6, lines 20-25).

Therefore, it would have been obvious to an artisan of at the time the invention was made to utilize Polysorbate 60 in the preparation of JP '343. One would have been motivated to do so since JP '343 teaches preparations comprising minoxidil and Peck suggests it as a stabilizer in quick-breaking foams comprising minoxidil. Thus, an artisan would have a reasonable expectation of success that the instant emulsifier would modify the surface tension and improve the physical stability of JP '343's minoxidil formulation.

Response to Arguments

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It is noted that the rejections above rely on a new primary reference, JP 10-265343. As such, applicant's arguments filed on 12/27/10 have been considered but are moot in view of the new ground(s) of rejection above.

Conclusion

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 29, and 139-163 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643